THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 25

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte JAMES M. PACHENCE, SALLY FRENKEL
and DAVID MENCHE

_____

Appeal No. 97-1192
Application 08/385,290[1]

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HEARD: July 15, 1999

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Before McQUADE, GONZALES and CRAWFORD, Administrative Patent Judges.

McQUADE, Administrative Patent Judge.

DECISION ON APPEAL

James M. Pachence et al. appeal from the final rejection of claims 1, 3, 4 and 6 through 10. Claims 2 and 5, which have been indicated by the examiner as containing allowable subject matter, stand objected to as depending from rejected

[1] Application for patent filed February 10, 1995.

base claims. Claims 11 through 16, the only other claims pending in the application, stand withdrawn from consideration pursuant to 37 CFR § 1.142(b).

The invention relates to a template for the regenerative repair of cartilage defects. Claim 1 is illustrative and reads as follows:

1. A template for the repair of cartilage defects leading to the regeneration of hyaline-like cartilage, the template comprising:

a) a first layer comprising a dense collagen membrane having a pore size of less than 1 micrometer which is cross-linked with a non-cytotoxic agent to increase strength and lengthen resorption time, to provide a barrier against movement of cells from the subchondral plate, the membrane being sufficiently permeable to allow the passage therethrough of fluids, nutrients, cytokines, and other endogenous factors necessary for healing; and

b) a second layer secured to the first layer and comprising a porous collagen matrix having pore size of 50 to 200 micrometers, which permits the ingrowth of cells.

The references relied upon by the examiner as evidence of obviousness are:

Lyng 3,526,228 Sept. 1, 1970

Tomoatsu Kimura et al., "Chondrocytes Embedded in Collagen Gels Maintain Cartilage Phenotype During Long-term Cultures," Clinical Orthopaedics, Vol. 186, pp. 231-39 (June 1984) (Kimura)

Claims 1, 3 and 7 through 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over Lyng, and claims 4 and 6 stand rejected under 35 U.S.C. § 103 as being unpatentable over Lyng in view of Kimura.

Reference is made to the appellants' brief (Paper No. 20) and to the examiner's answer (Paper No. 21) for the respective positions of the appellants and the examiner with regard to the merits of these rejections.

Lyng discloses a collagen fabric/film laminate that can be used as a prosthesis in reparative surgery. In Lyng's words,

> an improved prosthesis can be constructed using as a framework or support a collagen fabric woven, knitted, crocheted or braided of collagen strands. The collagen strands may be tanned either prior to manufacture of the fabric or subsequent thereto. In the prosthesis of the present invention the interstices between the collagen strands are filled and rendered bloodtight by tanned collagen fibrils, which form a sheet of film that is laminated to at least one surface of the fabric.
>
> It is an advantage of the prosthetic material of the present invention that it has a high tensile strength and is somewhat elastic when wet. The fabric layer of the laminate contributes good suture holding properties and the collagen fibril layer of the laminate provides a semi-permeable microbial barrier that is non-adhesiogenic. The prosthesis of the present invention is slowly absorbed with concomitant replacement by autologous fibrous tissue

[column 1, lines 34 through 50].

Lyng goes on to describe five specific examples (Examples I-V) of the laminate (see column 2, line 25 et seq.). The description of Example I includes a discussion of the fabric layer's weave.

In support of the rejection of independent claim 1, the examiner states that

> Lyng discloses a crosslinked collagen fabric, which constitutes the second layer as claimed, impregnated with a collagen film which constitutes the first layer as claimed, but Lyng fails to disclose the size of the pores thereof of the two layers. However, the Examiner asserts that the collagen film must have pores smaller than about 1 micron since it is semi-permeable and prevents microbes from passing through it; see the whole document, especially Col. 1, lines 27-50, Col. 2, lines 8-17 and Example I. Specifically, the Examiner reasons that, since the film membrane is semi-permeable, it allows fluids and small molecules therethrough. Furthermore, since microbes [are] on the order of about 1 micron in size, it seems reasonable to assume that the pores of Lyng are in the range of less than about 1 micron in size.
>
> With respect to the dimensions of the second layer of Lyng, the examiner posits that the fabric disclosed in Example I of Lyng would obviously result in pores size and thickness in the claimed range.
>
> Hence, it is the Examiner's position that the

> claimed invention is obvious in view of Lyng since none of the slight differences therefrom patentably distinguish it from Lyng [answer, pages 3 and 4].

Rejections based on 35 U.S.C. § 103 must rest on a factual basis. In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 177-78 (CCPA 1967). In making such a rejection, the examiner has the initial duty of supplying the requisite factual basis and may not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. Id.

As conceded by the examiner, Lyng does not expressly meet the pore size limitations in claim 1. The appellants' specification indicates that these pore sizes play an important role in accomplishing the stated objectives of the claimed template. The examiner's attempt to explain away Lyng's deficiencies in this regard is replete with speculation and unfounded assumptions having no reasonable foundation in the Lyng disclosure. We are therefore constrained to conclude that Lyng does not provide the factual basis necessary to justify the obviousness rejection of claim 1. Kimura, applied in a secondary capacity to support the rejection of dependent

claims 4 and 6, does not cure this fundamental flaw in the primary reference.

Accordingly, we shall not sustain the standing 35 U.S.C. § 103 rejection of independent claim 1 or of claims 3, 4 and 6 through 10 which depend therefrom.

The decision of the examiner is reversed.

REVERSED

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| JOHN P. McQUADE<br>Administrative Patent Judge | ) |
| MURRIEL E. CRAWFORD<br>Administrative Patent Judge | ) BOARD OF PATENT<br>) APPEALS AND<br>) INTERFERENCES |
| JOHN F. GONZALES<br>Administrative Patent Judge | ) |

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